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EXAMINER

PORTNER, VIRGINIA ALLEN

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1645

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11/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,459	Applicant(s) YOUNG ET AL.	
	Examiner GINNY PORTNER	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-35,37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 10-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9,33-35,37,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-4, 6-35, 37, 39-41 are pending.

Claims 1-4, 7-9 and 33-35, 37, 39-41 are under consideration.

Claims 6, 10-32 stand withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2008 has been entered.

Rejections/Objections Withdrawn

Claim Objections

1. **Withdrawn**, Claim 38 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, in light of the fact that the claim has been canceled.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. **Withdrawn**, The rejection of claims 33 and 34 as being directed compounds that are not isolated and purified compounds and therefore do not show the hand of man; the claimed invention is directed to non-statutory subject matter has been obviated by amending the claims to recite the phrase "isolated and purified"

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. **Withdrawn**, The rejection of claims 4 and 35 under 35 U.S.C. 112, first paragraph (New Matter), as failing to comply with the written description requirement, has been obviated by amending the claims to recite *Campylobacter jejuni* and *Campylobacter coli*.
6. **Withdrawn**, The rejection of claims 1,2, 4 and claims 33, 35 under 35 U.S.C. 102(a) as being anticipated by Linton et al (January 2002) in light of evidence provided by Szymanski et al (1999) has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".
7. **Withdrawn**, The rejection of claims 1-2, 7 and 9 and new claims 33-34, 37-38 and under 35 U.S.C. 102(e) as being anticipated by Bay et al has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".
8. **Withdrawn** The rejection of claims 1-3 and new claims 33-34 under 35 U.S.C. 102(e) as being anticipated by Pugia et al (filed June 12, 2002) has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".
9. **Withdrawn**, The rejection of claims 1-2, 7 and 9 and new claims 33, 37-38 under 35 U.S.C. 102(b) as being anticipated by Nilsson et al (Publication date 2000) has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".
10. **Withdrawn**, The rejection of claims 1-2, and new claim 33 under 35 U.S.C. 102(b) as being anticipated by Messner et al (1990) has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".
11. **Withdrawn**, The rejection of claims 1-2 and new claims 33 and 35 under 35 U.S.C. 102(b) as being anticipated by US Pat. 5,840,547 in light of evidence provided by Gutnick et al (US Pat. 6,512,014) has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".
12. **Withdrawn**, The rejection of claims 1, 7-9 and new claims 33, 37-40 under 35 U.S.C. 102(b) as being anticipated by Kaplan et al (WO 00/51635) in light of evidence provided by Gutnick et al (US Pat. 6,512,014), has been obviated in light of the claims no longer recite the phrase "or a fragment thereof".

Response to Arguments

1. Applicant's arguments filed September 9, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. ***Rejection Maintained***, The rejection of claims 1-4, 7-8, 37, 39 and claims 33-35, 39 under 35 U.S.C. 102(b) as being anticipated by Szymanski et al (1999) in light of evidence provided by Guerry et al (US PG-Pub 2007/0065461) is traversed by stating:

a. Szymanski et al describe obtaining the intact glycoprotein and the glycan portion of the glycoprotein was not purified nor isolated from the glycoprotein, nor the heptasaccharide linked to an amino acid or oligopeptide.

15. It is the position of the examiner that the compound of claim 1 is an isolated heptasaccharide(claim 1) that is conjugated to an amino acid (claims 2-3) and further comprises an immunoconjugate (claim 7, 39).

16. The compound of Szymanski et al comprises the heptasaccharide of claim 1 (in light of evidence provided by Guerry et al) linked to an amino acid (asparagine) in an immunoconjugate (PEB3 shown in isolated and purified form, together with the glycan (untreated, lane 1, bands shown in the 28-30 Kda range, page 1027, col. 1, top and ledger narrative). The pharmaceutically acceptable carrier was water (see page 1029, col. 1), this composition anticipates the instant claims because it was NOT deglycosylated and was an isolated and purified heptasaccharide immunoconjugated, the conjugate being PEB protein, linked to the heptasaccharide through Asparagine. PEB3 is highly immunogenic, a immunoconjugate

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(referred to as “immunodominant” in Szymanski et al, see page 1027, col. 2, last sentence bridging to page 1028) that comprises the instant heptasaccharide linked through an amino acid the immunoconjugate protein sequence.

17. The reference isolated C.jejuni saccharide, specifically a highly immunogenic glycan molecule that is linked to proteins, and in light of Guerri et al, one of Szymanski’s proteins was PEB3, an immunodominant glycoprotein/immunoconjugate that generates antibodies active against Campylobacter. Szymanski et al (1999) was an inherency rejection, and Guerri et al was cited as extrinsic evidence of the inherent characteristics of the Campylobacter jejuni glycan heptasaccharide immunoconjugate of Szymanski et al (1999).

18. See MPEP section 2124 that states "the critical date of extrinsic evidence showing a universal fact need not antedate the filing date." Guerri et al was used as extrinsic evidence to show the universal fact that the saccharide glycan of Campylobacter jejuni is in fact a heptasaccharide that is linked to numerous proteins through amino acids, the heptasaccharide being isolated from Campylobacter jejuni and was capable of generating antibodies active against Campylobacter jejuni. The prior art rejection is maintained for reasons of record and responses set forth herein. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, *the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new* to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Guerri et al, states [0008] One of the most unusual aspects of C. jejuni is the presence of a general system for N-linked glycosylation of numerous proteins (Szymanski et al., 1999; reviewed in Szymanski et al., 2003). This system, which includes an oligosaccharide transferase similar to that found in the eukaryote Saccharomyces cerevisiae, attaches a glycan which has recently been shown to be a heptasaccharide composed of one bacillosamine residue (an unusual deoxy sugar), one D-glucose, and five D-GalNAc residues (Young et al., 2002). The glycosylation appears to occur on numerous periplasmic, and perhaps, surface exposed proteins in C. jejuni (Young

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et al., 2002). The unusual glycan, again, appears to be highly immunogenic and is recognized during human infection (Szymanski et al., 1999, 2003).

Rangarajan et al (Protein Science 2007) also provides additional extrinsic evidence that the specific heptasaccharide of Szymanski et al, was in fact an immunoconjugate of the instantly claimed heptasaccharide linked to an Asn amino acid (see page 990, col. 1 and page 993, col. 1, lines 3-5 “attached to the Asn without rearrangement of the local protein structure”) conjugated to PEB3, a protein that is ~50% glycosylated (see page 991, col. 1, paragraph 2) at asparagine with the instantly claimed heptasaccharide.

New Claims/New Grounds of Rejection/Objection

Specification

19. The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

20. In Applicant's response dated August 7, 2008, a new abstract was submitted, but the title of the instant Application appeared on the same page as the abstract; only the abstract should be presented on a separate page.

Double Patenting

21. Claims 2-4 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 33-35. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Allowable Subject Matter

22. Claim 41 defines over the prior art of record and is therefore allowed.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1-4, 7-9, 33-35, 37, 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Blaser et al (US Pat. 5,470,958) in light of extrinsic evidence provided by Rangarajan et al (2007) .

25. Blaser et al disclose the instantly claimed invention directed to:

26. Instant claims 1-3, 8, 33-34, 39: an isolated and purified heptasaccharide linked through an amino acid as an immunoconjugate (PEB3, see col. 4, line 8, the immunoconjugate comprising an heptasaccharide (linked to an amino acid asparagine, and heptasaccharide are inherent characteristics of PEB3 as evidenced by Rangarajan et al, page 990, col. 1 and abstract), PEB3 was acid extracted (col. 4, lines 7-12) and further isolated and purified under native conditions (PEB3 col. 8, lines 1-4 and for PEB1 purification conditions see col. 6, line 36 and col. 16, Example 5 “Native Molecular Weight) by gel filtration under native conditions (see claim (col. 5, lines 48-58).

Instant claims 4, 35: obtained from either *Campylobacter coli* or *jejuni* (see col. 3, line 14).

Instant claims 7, 37: together with a pharmaceutically acceptable carrier (see col. 17, lines 3-21 and line 45 “buffer”, phosphate buffered saline (pH 7.4) (col. 17, line 52).

Instant claims 9, 40: and an adjuvant/immunostimulant (see col. 4, line 20; col. 17, line 44 “adjuvant”)

Blaser et al inherently anticipates the instantly claimed invention as now claimed.

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Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. □The Court further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

27. Claims 1-4, 7-8, 33-35, 37, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Pei et al (1991) in light of extrinsic evidence provided by Rangarajan et al (2007) .

28. Pei et al disclose the instantly claimed invention directed to:

29. Instant claims 1-3, 8, 33-34, 39: an isolated and purified heptasaccharide linked through an amino acid as an immunoconjugate (PEB3 (abstract) the immunoconjugate comprising an heptasaccharide (linked to an amino acid asparagine, and heptasaccharide are inherent characteristics of PEB3 as evidenced by Rangarajan et al, page 990, col. 1 and abstract, and page 991col. 1 paragraph 3 “A strong antigen (Pei et al.1991)”), PEB3 was acid extracted (page 16364, col. 1, paragraph 2) and further isolated and purified under native conditions (PEB3 “gel filtration chromatography (page 16364, col. 1, p. 2) by gel filtration under native conditions.

Instant claims 4, 35: obtained from either *Campylobacter jejuni* (see title).

Instant claims 7, 37: together with a pharmaceutically acceptable carrier (see page 16364, paragraph 2 “reconstituted with distilled water”).

Pei et al inherently anticipates the instantly claimed invention as now claimed. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court

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further held that □this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645

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November 21, 2008

/Mark Navarro/

Primary Examiner, Art Unit 1645